

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION

**FILED**

January 30, 2024  
CLERK, U.S. DISTRICT COURT  
WESTERN DISTRICT OF TEXAS

BY: \_\_\_\_\_ pg \_\_\_\_\_  
DEPUTY

NATIONAL INFUSION CENTER  
ASSOCIATION, on behalf of itself and its  
members; GLOBAL COLON CANCER  
ASSOCIATION, on behalf of itself and its  
members; and PHARMACEUTICAL RESEARCH  
AND MANUFACTURERS OF AMERICA, on  
behalf of itself and its members,

Plaintiffs,

vs.

XAVIER BECERRA, in his official capacity as  
Secretary of the U.S. Department of Health and  
Human Services, *et al.*,

Defendants.

Civil Action No. 1:23-cv-00707-DAE

**PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL  
AUTHORITY IN SUPPORT OF MOTION TO DISMISS**

The Government's notice of supplemental authority, ECF No. 50, exaggerates the significance of a *single example* of financial injury while continuing to ignore the procedural injuries that constitute the Complaint's gravamen. For two reasons, the "supplemental authority" has no effect on the standing analysis.

***First***, the Government's argument inverts the standing inquiry. Plaintiffs have shown that, as things currently stand, the IRA will cause NICA's members harm beginning in 2026 because there will be an MFP on Stelara that will reduce Medicare Part D reimbursements. Pls. Opp. 14. The Government falsely suggests that harm will occur only in 2028 when *Part B* reimbursements are affected. Defts' Notice of Supp. Auth 2. Because HHS in fact listed Stelara for Government-

imposed price caps, and that listing injures NICA starting in 2026, Plaintiffs are under no burden to *disprove* the Government’s assertion that the drug *might* later be deselected (an assertion that is entirely conjectural). Rather, it is *the Government* that must support its assertions that harm will be averted. Even if the Government might later introduce evidence to support this “possib[ility],” “[a]t the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

***Second***, financial harm from lower future drug reimbursements is not Plaintiffs’ principal claimed harm supporting standing. Though the Government tries to wish these allegations away, NICA alleges that “the IRA inflicts [harm] *now* by depriving NICA’s members of constitutionally required due process, impermissibly delegating legislative power to the agency, and coercing compliance via excessive fines.” Pls. Opp. to Mot. to Dismiss 6, ECF No. 47. Those are “here-and-now injur[ies],” *Axon Enter. v. FTC*, 598 U.S. 175, 192 (2023), that NICA is *already suffering* regardless of the details of any specific drug’s future reimbursements. The Government also ignores unrefuted allegations that the IRA is “already impacting the ability of NICA’s members to raise debt and equity funding for their operations,” Supp. Nyquist Decl. ¶ 20, ECF No. 47-2, another independently cognizable injury.

Plaintiffs respectfully submit that the Government’s motion to dismiss should be denied.

Dated: November 7, 2023

Respectfully submitted,

/s/ Michael Kolber

Michael Kolber\* (New York Bar No.  
4806527)  
MANATT, PHELPS & PHILLIPS LLP  
7 Times Square  
New York, NY 10036  
(212) 790-4568  
mkolber@manatt.com

Megan Thibert-Ind\* (Illinois Bar No.  
6290904)  
MANATT, PHELPS & PHILLIPS LLP  
151 N. Franklin St. Suite 2600  
Chicago, IL 60606  
(312) 477-4799  
mthibert-ind@manatt.com

*\*Admitted Pro Hac Vice*

*Counsel for Plaintiff Global Colon Cancer  
Association*

/s/ Tim Cleveland

Tim Cleveland (Texas Bar No. 24055318)  
Austin Krist (Texas Bar No. 24106170)  
Ibituroko-Emi Lawson (Texas Bar No.  
24113443)  
McKenzie Edwards (Texas Bar No.  
24116316)  
CLEVELAND KRIST LLC  
303 Camp Craft Road, Suite 325  
Austin, TX 78746  
(512) 689-8698  
tcleveland@clevelandkrist.com

*Counsel for Plaintiff National Infusion Center  
Association*

/s/ Allissa Pollard

Allissa Pollard (Texas Bar No. 24065915)  
ARNOLD & PORTER KAYE SCHOLER  
LLP  
700 Louisiana Street, Suite 4000  
Houston, TX 77002  
(713) 576-2451  
allissa.pollard@arnoldporter.com

Jeffrey Handwerker\* (D.C. Bar No. 451913)  
John Elwood\* (D.C. Bar No. 452726)  
Allon Kedem\* (D.C. Bar No. 1009039)  
William Perdue\* (DC Bar No. 995365)  
ARNOLD & PORTER KAYE SCHOLER  
LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
(202) 942-5000  
jeffrey.handwerker@arnoldporter.com

*\*Admitted Pro Hac Vice*

*Counsel for Plaintiff Pharmaceutical Research  
and Manufacturers of America*